

CLAIMS

1. An injectable composition comprising a combination of 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole (lansoprazole), its optically active compound or a salt thereof, and a chelating agent, which is used at pH 9 to 12.

2. The injectable composition according to claim 1, which comprises a strong alkali in an amount of about 1 to 10 about 3 equivalent relative to one mol of lansoprazole or its optically active compound.

3. The injectable composition according to claim 2, which further comprises N-methylglucamine.

4. The injectable composition according to claim 3, wherein the amount of N-methylglucamine is about 0.1 mg to 15 about 1 mg relative to 1 mg of lansoprazole, its optically active compound or a salt thereof.

5. An injectable composition comprising a solution of lansoprazole, its optically active compound or a salt thereof and a chelating agent, which is substantially free 20 of insolubles and filled in a container, and which is used of insolubles and filled in a container, and which is used at pH 9 to 12.

6. The injectable composition according to claim 5, wherein lansoprazole, its optically active compound or a salt thereof, and the chelating agent are separately stored 25

and kept, and they are mixed at the time of using the composition.

7. The injectable composition according to claim 5, which is filled in a plastic container made of a polyethylene, a polypropylene, a copolymer of polyethylene and polypropylene, a polyvinyl chloride, a copolymer of ethylene and vinyl acetate, a copolymer of ethylene and propylene, a silicone, a polybutadiene, a thermoplastic elastomer, Teflon (Registered Trade Mark), a polyurethane, 10 a cyclic polyolefin or a polyolefin.

8. The injectable composition according to claim 1, wherein the chelating agent is edetic acid or its salt or a derivative thereof; phosphoric acid or its salt; or citric acid or its salt.

15 9. The injectable composition according to claim 1, wherein the chelating agent is a sodium salt of edetic acid.

10. The injectable composition according to claim 1, wherein edetic acid or its salt is contained as the chelating agent in an amount corresponding to about 0.03 % 20 to about 67 % by weight relative to lansoprazole, its optically active compound or a salt thereof.

11. The injectable composition according to claim 1, which has pH of about 10.4 to about 12.0, when it is dissolved in a physiological saline or distilled water for 25 injection in a proportion of 5 ml thereof relative to 30 mg

of lansoprazole, its optically active compound or a salt thereof.

12. The injectable composition according to claim 1, which is a freeze-dried preparation.

5 13. The injectable composition according to claim 1, which further comprises a saccharide.

14. The injectable composition according to claim 13, wherein the saccharide is a sugar alcohol.

10 15. The injectable composition according to claim 13, wherein the saccharide is mannitol.

15 16. The injectable composition according to claim 13, wherein the saccharide is contained in a proportion of about 0.1 mg to about 20 mg relative to 1 mg of lansoprazole, its optically active compound or a salt thereof.

20 17. The injectable composition according to claim 1, which contains about 3 mg to about 10 mg of sodium hydroxide, about 8 mg to about 24 mg of N-methylglucamine, about 50 mg to about 70 mg of mannitol and about 0.009 mg to about 20.1 mg of disodium edetate relative to 30 mg of lansoprazole, its optically active compound or a salt thereof.

25 18. An injectable composition which is prepared by adding an aqueous or a non-aqueous solvent containing edetic acid or its salt to a freeze-dried injectable

preparation containing 30 mg of lansoprazole, its optically active compound or a salt thereof, about 3 mg to about 10 mg of sodium hydroxide, about 8 mg to about 24 mg of N-methylglucamine and 60 mg of mannitol.

5 19. The injectable composition according to claim 1, which is for preventing or treating peptic ulcer, gastroesophageal reflux disease; gastritis; Zollinger-Ellison disease syndrome; NUD (Non Ulcer Dyspepsia); gastric cancer; gastric MALT lymphoma; upper 10 gastrointestinal hemorrhage due to gastric ulcer, duodenal ulcer, acute gastroduodenal ulcer and acute gastric mucosal lesion, ulcer caused by a nonsteroidal anti-inflammatory agent; hyperacidity and ulcer due to postoperative stress; upper gastrointestinal hemorrhage due to invasive stress; 15 gastritis atrophicans after operation of endoscopic demucosation against early gastric cancer; hyperplastic polyp; idiopathic thrombocytopenic purpura; a disease due to *Helicobacter pylori*; asthma due to gastric acid reflux, sleep disorder due to gastric acid reflux; abdominal pain 20 due to GERD; Laryngitis; chronic obstructive pulmonary disease (COPD); obstructive apneusis; and Barrett's esophagus.

25 20. A method for preventing or treating peptic ulcer, gastroesophageal reflux disease; gastritis; Zollinger-Ellison disease syndrome; NUD (Non Ulcer Dyspepsia);

gastric cancer; gastric MALT lymphoma; upper 5
gastrointestinal hemorrhage due to gastric ulcer, duodenal
ulcer, acute gastroduodenal ulcer and acute gastric mucosal
lesion, ulcer caused by a nonsteroidal anti-inflammatory
agent; hyperacidity and ulcer due to postoperative stress;
upper gastrointestinal hemorrhage due to invasive stress;
gastritis atrophicans after operation of endoscopic
demucosation against early gastric cancer; hyperplastic
polyp; idiopathic thrombocytopenic purpura; a disease due to
10 *Helicobacter pylori*; asthma due to gastric acid reflux,
sleep disorder due to gastric acid reflux; abdominal pain
due to GERD; Laryngitis; chronic obstructive pulmonary
disease (COPD); obstructive apneusis; and Barrett's
esophagus, which comprises administering the injectable
15 composition according to claim 1 to a human being.

21. Use of the injectable composition according to
claim 1 for preventing or treating peptic ulcer,
gastroesophageal reflux disease; gastritis; Zollinger-
Ellison disease syndrome; NUD (Non Ulcer Dyspepsia);
20 gastric cancer; gastric MALT lymphoma; upper
gastrointestinal hemorrhage due to gastric ulcer, duodenal
ulcer, acute gastroduodenal ulcer and acute gastric mucosal
lesion, ulcer caused by a nonsteroidal anti-inflammatory
agent; hyperacidity and ulcer due to postoperative stress;
upper gastrointestinal hemorrhage due to invasive stress;
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gastritis atrophicans after operation of endoscopic demucosation against early gastric cancer; hyperplastic polyp; idiopathic thrombocytopenic purpura; a disease due to *Helicobacter pylori*; asthma due to gastric acid reflux, 5 sleep disorder due to gastric acid reflux; abdominal pain due to GERD; Laryngitis; chronic obstructive pulmonary disease (COPD); obstructive apneusis; and Barrett's esophagus.